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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,464	02/28/2002	Daphne Goring	P 25,762-A USA	2392

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,464	GORING ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary amendments

The preliminary amendments filed February 28, 2002, March 5, 2002, and July 8, 2002 have been entered.

Specification

The abstract is objected to because it fails to make reference to the methods for producing a transgenic plant which are claimed. Appropriate correction is required.

The disclosure is objected to because the information at page 1 describing the relationship between the instant application and previously filed applications is incorrect. The preliminary amendment March 5, 2002 amended the specification to delete the paragraph starting at page 1 line 3 and replaced it with the following paragraph before the heading "Field of the Invention" .

---This is a U.S. national stage application based on international Application No. PCT/CA00/00966, filed August 18, 2000, which claims priority to U.S. provisional Application No. 60/149,466, filed August 19, 1999, and to U.S. provisional Application No. 60/159, 122, filed October 13, 1999.--

The preliminary amendment March 5, 2002 asserts that the above amendment was made to correct a clerical error made in the prior preliminary amendment in which the present application was purportedly misidentified as being a continuation-in-part of international Application No. PCT/CA00/00966, when in fact it is a national stage application based thereon. A review of the record indicates that the present application is not a national stage application

based on Application No. PCT/CA00/00966. The Utility Patent Application Transmittal form for the present application at page 1 identifies the present application as "transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b)". The Utility Patent Application Transmittal form for the present application at page 1 also identifies the present application as a Continuation-in-part of prior application No. not yet assigned filed under Express Mail Label No. EL930922731US, now U.S. Application No. 10/069,304, filed August 6, 2002, which is a national stage application based on Application No. PCT/CA00/00966. Appropriate correction of the information at page 1 describing the relationship between the instant application and previously filed applications is required.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed March 31, 2003 is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to plant transformation methods wherein a plant is transformed with an isolated nucleic acid molecule encoding any PERK polypeptide of unspecified structure obtained from any unspecified source, or any polypeptide of unspecified structure obtained from any unspecified source having PERK activity, and to plant transformation methods wherein a plant is transformed with isolated nucleic acid molecules that hybridize to a nucleic acid molecule consisting of all or any unspecified part of SEQ ID NO:1 or a complement thereof under low, moderate or high stringency hybridization conditions, and molecules degenerate thereto; isolated nucleic acid molecules of the coding strand shown in SEQ ID NO: 1, or a complement thereof or encoding the same amino acid sequence as SEQ ID NO:1; and isolated nucleic acid molecules having at least 17 % identity with SEQ ID NO:1.

The specification describes a single 2189 base pair full length cDNA sequence of SEQ ID NO:1 designated PERK1 (Proline-rich Extensin-like Receptor Kinase 1), which was obtained from a *Brassica napus* pistil cDNA library using primers designed against the conserved kinase subdomains I and VII of receptor-like protein kinases, wherein said sequence consists of one large open reading frame of 1944 bp encoding a 648 amino acid protein of SEQ ID NO:2 (page 47 lines 10-27). The specification also describes PERK1 as defining a new class of plant receptor kinases characterized by an extracellular domain rich in proline sharing sequence similarity to the extensin family of cell wall proteins (page 4 lines 1-8). The specification does not describe other nucleic acid molecules obtained from other sources that encode a PERK polypeptide or a polypeptide having PERK activity, such as nucleic acid molecules that that hybridize to a nucleic

acid molecule consisting of all or part of SEQ ID NO:1 or a complement thereof under low, moderate or high stringency hybridization conditions, or isolated nucleic acid molecules having at least 17 % identity with SEQ ID NO:1. The specification also does not describe or define the nature of the "PERK activity" exhibited by the encoded polypeptides. The specification further does not describe the structural features of SEQ ID NOS:1 or 2 that are characteristic of PERK sequences or that are correlated with PERK activity, such as conserved amino acid motifs or conserved functional domains unique to PERK sequences.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus that encompasses isolated nucleic acid molecules that encode any PERK polypeptide of unspecified structure obtained from any unspecified source, or any polypeptide of unspecified structure obtained from any unspecified source having PERK activity, nor the structural features unique to the genus. Applicant also has not described a representative number of species falling within the scope of the claimed genus that encompasses isolated nucleic acid molecules that hybridize to a nucleic acid molecule consisting of all or any unspecified part of SEQ ID NO:1 or a complement thereof under low, moderate or high stringency hybridization conditions, nor the structural features unique to the genus.. Applicant

additionally has not described a representative number of species falling within the scope of the claimed genus that encompasses isolated nucleic acid molecules having at least 17 % identity with SEQ ID NO:1, nor the structural features unique to the genus.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plant transformation methods wherein a plant is transformed with an isolated nucleic acid molecule of SEQ ID NO:1 or an isolated nucleic acid molecule encoding SEQ ID NO:2, does not reasonably provide enablement for plant transformation methods using other nucleic acid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to plant transformation methods wherein a plant is transformed with an isolated nucleic acid molecule encoding any PERK polypeptide of unspecified structure obtained from any unspecified source, or any polypeptide of unspecified structure obtained from any unspecified source having PERK activity, including a method in which plant height, number of branches, number of seed pods and/or seed production compared to wild-type plants in the plant are increased or wherein the plant has quicker flowering or later senescence. The claims are also drawn to plant transformation methods wherein a plant is transformed with isolated nucleic acid molecules that hybridize to a nucleic acid molecule consisting of all or any unspecified part of SEQ ID NO:1 or a complement thereof under low, moderate or high stringency hybridization conditions, and molecules degenerate thereto; isolated nucleic acid molecules of the coding strand shown in SEQ ID NO: 1, or a complement thereof or encoding

the same amino acid sequence as SEQ ID NO:1; and isolated nucleic acid molecules having at least 17 % identity with SEQ ID NO:1.

With respect to isolated nucleic acid molecules encoding PERK polypeptides, the specification discloses the cloning of a single 2189 base pair full length cDNA sequence of SEQ ID NO:1 designated PERK1 (Proline-rich Extensin-like Receptor Kinase 1), which was obtained from a *Brassica napus* pistil cDNA library using primers designed against the conserved kinase subdomains I and VII of receptor-like protein kinases, wherein said sequence consists of one large open reading frame of 1944 bp encoding a 648 amino acid protein of SEQ ID NO:2 (page 47 lines 10-27). The specification also discloses that the deduced amino acid sequence of PERK1 shows that it is a transmembrane receptor kinase with a distinct extracellular, transmembrane and cytoplasmic domain (Figure 1), and that the extracellular domain of PERKI shows sequence similarity to plant cell wall proline-rich proteins and extensins which comprise a family of hydroxproline-rich glycoproteins (page 21 lines 19-26). The specification additionally discloses that PERK1 defines a new class of plant receptor kinases (page 4 lines 1-8), and that the catalytic domain of PERKI possesses all of the invariant residues necessary for kinase activity (page 22 lines 8-9). The specification does not disclose the identification, cloning or use of other nucleic acid molecules encoding other polypeptides having the characteristics of the *Brassica napus* PERK1 polypeptide.

With respect to the transformation of plants with isolated nucleic acid molecules encoding PERK polypeptides, the specification discloses the transformation of *Arabidopsis thaliana* and *Brassica napus* plants with the *Brassica napus* PERK1 nucleic acid of SEQ ID NO:1 operably linked to a 35S CaMV promoter in a sense orientation (pages 45-46). *Arabidopsis*

plants transformed with the *Brassica napus* PERK1 nucleic acid of SEQ ID NO:1 exhibited several heritable traits including enhanced growth and fertility (Figure 16B), with the S2, S4 and S1n independent lines showing increased height and secondary branching compared to the wild-type plants (Figure 16B, 18B). The pistils of overexpressing PERK1 sense plants also exhibited an altered phenotype when compared to pistils of wild-type *Arabidopsis* plants, in that the papillae cells at the surface of the stigma appear elongated (Figure 17), and the enhanced growth/height apparent in these overexpressing plants was the result of cell expansion rather than increased cell division (page 46 first full paragraph). The overexpressing PERK1 lines also showed an extended life cycle with the plants flowering earlier and senescing later than the wild-type plants (page 46 second full paragraph). In addition, there was no decrease in the fertility or seed viability in these lines, with the overexpressing PERK1 lines showing an increase in the total number of siliques (seed pods) per plant and an increase in the number of seeds per silique (Figure 18A), resulting in an increase in the dry seed weight per plant (Figure 18A). The dry seed weight per plant for the overexpressing PERK1 lines was approximately twice as much as for wild-type plants (Figure 18A), and the phenotypes observed in these lines were stable for 3 generations (page 46 second full paragraph). *Brassica napus* plants transformed with the *Brassica napus* PERK1 nucleic acid of SEQ ID NO:1 flowered at an earlier age than wild type plants (page 46 lines 22-26).

The full scope of the claimed invention is not enabled because the specification does not provide sufficient guidance with respect to where and how to obtain other isolated nucleic acid molecules encoding PERK polypeptides obtained from sources other than *Brassica napus* plants.

Such guidance is necessary because one cannot predictably obtain PERK polypeptides from other sources.

The specification discloses that the *Brassica napus* PERK1 polypeptide is a receptor-like protein kinase, which proteins are known to exhibit diversity with respect to their specific functions in plants, such that a PERK polypeptide could not be predictably selected on the basis of its identity as a receptor-like protein kinase alone. Applicant's own specification makes note of this diversity. For example, at page 2 lines 1-7 it is disclosed that "members of the plant RLK family share highly conserved catalytic domains known to possess serine/threonine substrate specificity, yet the extracellular domains of these receptors are quite divergent which enable these proteins to selectively respond to diverse extracellular signals (Lease et al., 1998; Walker, 1994). There are several classes of plant RLKs distinguished according to characteristic amino acid sequence motifs of their extracellular domains (Shiu and Bleecker, 2001)".

The prior art further teaches that even plant RLKs that share the same characteristic amino acid sequence motifs in their extracellular domains can differ in function. For example, Song et al. teach that the rice disease resistance gene Xa21 encodes a receptor-like protein kinase having an extracellular domain comprising a leucine rich repeat, which receptor-like protein kinase confers resistance to *Xanthomonas oryzae* pv. oryzae race 6 (Science, 1995 Dec 15; 270(5243): 1804-6, Applicant's IDS). Alternatively Clark et al. teach that the *Arabidopsis CLAVATA* gene encodes a receptor-like protein kinase having an extracellular domain comprising a leucine rich repeat, which receptor-like protein kinase functions to controls shoot and floral meristem size (Cell, 1997 May 16; 89(4): 575-85, Applicant's IDS).

Given the diverse specific functions exhibited by different receptor-like protein kinases in plants, it would require undue experimentation for one skilled in the art to identify and clone from undisclosed sources sequences encoding polypeptides having homology to the *Brassica napus* PERK1 polypeptide, as one skilled in the art would have to test by trial and error the effect of expressing each homologous sequence he or she obtains on the phenotype of a plant transformed therewith.

Given the claim breadth which encompasses the use of any isolated nucleic acid molecule encoding any PERK polypeptide of unspecified structure obtained from any unspecified source whose expression in a plant transformed therewith would result in increased plant height, number of branches, number of seed pods and/or seed production compared to wild-type plants or quicker flowering or later senescence, given the unpredictability in obtaining isolated nucleic acid molecules encoding PERK polypeptides from other sources as discussed above, and given the lack of guidance as discussed above, it would have required undue experimentation for one skilled in the art to make and use the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanksley et al. (US Patent No. 5,648,599, issued July 15, 1997).

Claim 1 is drawn to a method for producing a transgenic plant having increased plant height, number of branches, number of seed pods and/or seed production compared to a non-transgenic plant, and/or quicker flowering or later senescence, compared to a non-transgenic plant, comprising transforming a plant with a vector including an isolated nucleic acid molecule encoding any PERK polypeptide of unspecified structure obtained from any unspecified source, or any polypeptide of unspecified structure obtained from any unspecified source having PERK activity. Claims 3-4 are drawn to the method of claim 1 wherein the nucleic acid molecule hybridizes to a nucleic acid molecule consisting of all or part of SEQ ID NO:1 or a complement thereof under low, moderate or high stringency hybridization conditions, or wherein the nucleic acid molecule has at least 17 % identity with SEQ ID NO:1. Claim 5 is drawn to the method of claim 1 wherein the plant is a tomato plant.

Tanksley et al. a method for producing a transgenic tomato plant comprising transforming a plant with a vector including an isolated nucleic acid molecule corresponding to Tanksley et al.'s SEQ ID NOS:1, 2 and 3 encoding a serine/threonine protein kinase obtained from tomato (column 17 lines 19-61; column 28 lines 48-61). The isolated nucleic acid molecules corresponding to Tanksley et al.'s SEQ ID NOS: 2 and 3 have at least 17 % identity with Applicant's SEQ ID NO:1, as Tanksley et al.'s SEQ ID NOS: 2 and 3 and Applicant's SEQ ID NO:1 have a best local similarity of 50.7% (see attached sequence alignment). Tanksley et al.'s SEQ ID NOS: 2 and 3 accordingly would also hybridize to a nucleic acid molecule consisting of all or part of Applicant's SEQ ID NO:1 or a complement thereof under low, moderate or high stringency hybridization conditions. The isolated nucleic acid molecules corresponding to Tanksley et al.'s SEQ ID NOS: 2 and 3 encode a PERK polypeptide having

PERK activity because they, like Applicant's SEQ ID NO:1, encode a serine/threonine protein kinase. While Tanksley et al. do not teach the production of a transgenic plant having increased plant height, number of branches, number of seed pods and/or seed production compared to a non-transgenic plant, and/or quicker flowering or later senescence, compared to a non-transgenic plant, Tanksley et al. need not teach the production of such plants, as the recitation of these characteristics in the preamble of the claim is interpreted as an intended use for the method claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (Cell, 1997, Vol. 90, pages 929-938, Applicant's IDS) in view of Mandel et al. (Nature, 1995, Vol. 377, pages 522-524).

Claim 2 is drawn to a method for producing a transformed plant comprising cloning or synthesizing a nucleic acid molecule encoding any PERK polypeptide of unspecified structure obtained from any unspecified source, or any polypeptide of unspecified structure obtained from any unspecified source having PERK activity, inserting said nucleic acid molecule into a vector such that it is operably linked to a promoter, inserting said vector into a plant cell or seed, and regenerating a plant wherein plant height, number of branches, number of seed pods and/or seed

production compared to wild-type plants in the plant are increased or wherein the plant has quicker flowering or later senescence. Claims 6-7 are drawn to the method of claim 2 wherein the nucleic acid molecule hybridizes to a nucleic acid molecule consisting of all or part of SEQ ID NO:1 or a complement thereof under low, moderate or high stringency hybridization conditions. Claim 8 is drawn to the method of claim 2 wherein the plant is *Arabidopsis*.

Li et al. teach cloning a nucleic acid molecule encoding BRI1, a receptor protein kinase obtained from *Arabidopsis* (page 930 column 2 second full paragraph through page 933 column 1 first full paragraph). Li et al. teach that *Arabidopsis* plants having mutations in the gene encoding BRI1 exhibit a dwarf phenotype, indicating that that BRI1 is required for plant growth (page 929 Summary). The nucleic acid molecule encoding BRI1 taught by Li et al. would hybridize to a nucleic acid molecule consisting of all or part of Applicant's SEQ ID NO:1 or a complement thereof under low, moderate or high stringency hybridization conditions, because the nucleic acid molecule encoding BRI1 taught by Li et al. encodes a protein having the conserved kinase subdomains I and VII of receptor-like protein kinases, which conserved kinase subdomains are present in the protein encoded by Applicant's SEQ ID NO:1 (page 933 Figure 5). The nucleic acid molecule encoding BRI1 taught by Li et al. encodes a PERK polypeptide having PERK activity because, like Applicant's SEQ ID NO:1, it encodes a receptor-like protein kinase.

Li et al. do not teach inserting a nucleic acid molecule encoding BRI1 into a vector such that it is operably linked to a promoter, inserting said vector into a plant cell or seed, and regenerating a plant wherein plant height, number of branches, number of seed pods and/or seed

production compared to wild-type plants in the plant are increased or wherein the plant has quicker flowering or later senescence.

Mandel et al. teach a nucleic acid molecule encoding APETALA1, a transcription factor protein identified by loss of function mutational analysis and obtained from *Arabidopsis*. Mandel et al. teach that the decision to form flowers instead of shoots is mediated in *Arabidopsis* by the action of floral-meristem identity genes, such as APETALA1, which specify meristem fate (page 522 abstract). Mandel et al. teach inserting a nucleic acid molecule encoding APETALA1 into a vector wherein the nucleic acid molecule is operably linked to a 35S CaMV promoter, inserting said vector into wild-type *Arabidopsis* plants, and regenerating transgenic *Arabidopsis* plants wherein overexpression of the APETALA1 protein prematurely converts inflorescence shoot meristems into flowers (page 523 Figure 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made that a nucleic acid molecule encoding a BRI1 PERK polypeptide as taught by Li et al. could be inserted into a vector operably linked to a promoter and used to transform wild type plants to obtain plants, wherein both PERK activity and its effect on plant phenotype (height) are increased as compared to nontransformed wild type plants. One of ordinary skill in the art would have been motivated to do so to further characterize and confirm the specific function of the PERK coding sequence in planta. One of ordinary skill in the art would have had a reasonable expectation of success, given that gain of function analysis was known and successfully used in the art at the time of filing, as taught by Mandel et al., and given that mutations in BRI1 indicate that BRI1 would promote plant growth (height), as taught by Li et al.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  7/13/04